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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,948	08/28/2003	James J. Langan	71202-0030	1947
20915	7590	06/01/2006	EXAMINER	
MCGARRY BAIR PC 171 MONROE AVENUE, N.W. SUITE 600 GRAND RAPIDS, MI 49503				CHENG, JACQUELINE
		ART UNIT		PAPER NUMBER
		3768		

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/604,948	LANGAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 August 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-59 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/28/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 20, 23, and 40-52 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,685,666 B1 (herein referred to as Fontenot).

**Claims 1, 20, 23, 35-37, 49-52:** Fontenot discloses invasive methods and devices which position and anchor single or multiple lumen (which are fluidly isolated) catheters proximate to breast lesions under radiographic guidance (col. 1 line 8-15). The catheter comprises a hook wire that is fixed to the distal part and can comprise ports to allow any type of fluid to exit the catheter lumen and flow into the surrounding tissues. The hook wire is used to engage the breast and become anchored in the breast tissue. The catheter has radiopaque markers that can be placed along the length of the catheter so that, when imaged, the depth of placement can be determined (col. 6 line 40-42) and proper placement of the catheter is ensured (col. 6 line 61-62).

**Claim 30-34:** The shape and configuration of the outlet ports is a design choice. Any size, shape and configuration of the ports that allow the fluid to flow to the tissue can be used. An example of a circular, 90 degrees radially spaced ports can be seen in figure 4 of US Patent No. 6,261,240

B1, Carlson et al. Carlson et al. also discloses explicitly in col. 3 line 10-14, that “sizes appropriate to the specific application, and the number and arrangement of perforations will necessarily vary from the disclosed preferred embodiment.

**Claims 38-42:** The type of imaging marker that is used and its placement is a design choice. For example US Publication No. 2002/0188196 A1 discloses that radiopaque materials shaped such as bands, strips, and coils, and made of material such as tungsten, can be used to detect the marked object using radiographic imaging techniques (paragraph 0041).

**Claim 43:** The medical device of Fontenot discloses a needle for locating the infusion tube into the tissue (fig. 7).

**Claims 44-48:** A syringe is releasably connected to a transparent catheter for the delivery of fluid through the lumen of the catheter.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-19 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot as applied to claim1 above, and further in view of US Patent No. 5,782,771 (herein referred to as Hussman).

**Claims 2, 3, 6, 7, and 24-29:** Although Fontenot does not expressly disclose how the hook wire is fixed it would be obvious to one skilled in the art to use any method to securely fix the hook to the catheter. Hussman expressly discloses some methods of fixing a hook wire to a localization fiber. The hook is affixed to the tip of the fiber, by adhesive, integration with the cladding or coating, or by a variety of other conceivable means (col. 4 line 39-43). One of such methods is to have a hookwire that runs down the shaft and is held on by fasteners (col. 5 line 23-29). Another is to use the actual fiber optic as the hook and hook wire (col. 5 line 15-20). It would be obvious to combine Hussman with Fontenot et al. as both inventions have a hook wire, fixed to a medical instrument, for use in anchoring into breast tissue.

**Claims 4, 5, and 14-16:** Fontenot discloses radiopaque markers that can be placed along the length of the catheter so that, when imaged, the depth of placement can be determined (col. 6 line 40-42). These radiopaque markers are capable of being of any shape or form, such as a bead.

**Claims 8-11, 17-19:** Fontenot discloses holes in the lumen that allows fluid, such as an anesthetic, to flow out of the lumen. The fluid is introduced into the lumen by placing a syringe at the inlet (fig. 12). The shape and spacings of the outlet ports are a design choice. Fontenot does show in figure 1c and 12 ports radially spaced about the infusion tube.

**Claims 12 and 13:** Fontenot discloses the hook being flexible, as the arms of the hook are compressed against the wall of the needle until placed proximate to the breast lesion. Fontenot also discloses this hook wire as being able to be reversibly placed (col. 6 line 44-50).

5.     **Claims 21, 22 and 53-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontenot as applied to claims 20 and 49 above, and further in view of US Patent No. 6,261,240

B1 (herein referred to as Carlson et al.). Carlson et al. discloses a hollow localization wire having an anchoring hook at its distal end. The localization wire is inserted in place, by use of a loading needle. Once the wire is in place, the needle is removed, the hook is released and the wire is anchored into the breast tissue. A syringe attachment can be affixed to the proximal end of the hollow wire to inject radioactive material such as Gadolinium (which is a well-known radioactive fluid used as an imaging marker). The radioactive material, injected around the cancerous tumor in the breast, will move to the first draining lymph node (the sentinel node). This movement is imaged to localize where that node is located. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Carlson et al. with Fontenot as both methods are used for localizing tumors in the breast using radiopaque marked methods with an anchored infusion tube, for delivering a fluid to the site.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC



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